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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,730	09/16/2005	Evert Johannes Bunschoten	0470-050738	1144

7590 11/25/2008
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EXAMINER

JAVANMARD, SAHAR

ART UNIT	PAPER NUMBER
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1617

MAIL DATE	DELIVERY MODE
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11/25/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/526,730	Applicant(s) BUNSCHOTEN ET AL.	
	Examiner SAHAR JAVANMARD	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17, 20, 21, 23, 25-28 and 30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17, 20, 21, 23, 25-28, and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 15, 2008 has been entered.

Claim(s) 17, 20, 21, 23, 25-28, and 30 are pending and are examined herein.

In view of Applicant's amendments with respect to the 112 1st rejection with regard to prophylaxis, the rejection is hereby withdrawn.

Applicant's arguments with respect to the 103(a) rejection of claims 17, 20, 21, 23 and 25-30 as being unpatentable over Place (US Patent 6,117,446) in view of Yamazaki (*Archive of Biochemistry and Biophysics*, 1997) have been fully considered but found not persuasive. Applicant is arguing based on amended claims.

The new rejections are included in the office action below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17, 20, 21, 23, 25-28, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Place (US Patent 6,117,446) as evidenced Yamazaki (*Archive of Biochemistry and Biophysics*, 1997).

Place teaches a buccal drug delivery system that may be used in female hormone replacement therapy, in female contraception and to treat female sexual dysfunction (abstract). Place teaches that the pharmaceutical compositions comprise a therapeutic amount of an androgenic agent, a progestin, an estrogen, and a bioerodible polymeric carrier (column 4, lines 4-11).

Place further teaches that the buccal dosage units are in the form of tablets in amounts of 0.1 to about 2.5 mg of the selected androgenic agent, preferably testosterone or a testosterone ester, about 300 to 5000 μg progestin and about 50 to 500 μg estrogen.

Furthermore, Place teaches that among a number of androgenic agents that may be employed, naturally occurring androgens and derivatives thereof may also be used in the formulations (column 7, lines 11-15), specifically, testosterone (column 7, line 28).

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As evidenced by Yamazaki, 15-hydroxytestosterones are naturally occurring androgens in the body. Specifically, Yamazaki teaches that when testosterone is exposed to liver microsomes or recombinant P450 enzymes, 15 α and β -hydroxytestosterones are identified as metabolites (page 167, Table III).

Thus, testosterone, the precursor to 15-hydroxytestosterone, as evidenced by Yamazaki, anticipates the instant claims.

Conclusion

Claims 17, 20, 21, 23, 25-28, and 30 are not allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAHAR JAVANMARD whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/S. J./

Examiner, Art Unit 1617

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617